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No. 03-388

Supreme Court, U.S.
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In The
Supreme Court of the United States

DENNIS BATES, et al.,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF FOR HERBERT SAMUEL HARRISON AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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QUESTION PRESENTED

Which, if any, state law crop injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§136-137?

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

Herbert Samuel Harrison respectfully submits this brief as *amicus curiae* in this case.[1]

Harrison earned a Bachelor of Science in Professional Agriculture from Berea College in 1955 and a Masters of Agriculture from the University of Florida in 1958. He served as a Program Specialist in the United States Department of Agriculture ("UDSA") Pesticide Registration Divisions Office of Pesticide Programs ("OPP") from 1967 until 1970. In that position, he coordinated scientific and regulatory review of applications for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). After creation of the United States Environmental Protection Agency ("EPA") by executive order in 1970, regulatory oversight of pesticides was transferred from the USDA to the EPA.

From 1970 to 1971, Harrison was the Chief of the Ecological Investigations Branch of the EPA where he developed a program to investigate the adverse effects of pesticides. In 1971, he was promoted to Chief of the Insecticide and Rodenticide Branch of the EPA where he and his staff coordinated the scientific and regulatory review of applications for pesticide registration, reregistration, amended registration, and experimental use permits. He served in that capacity for 21 years, after which he became Special Assistant to the Director, responsible for

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[1] Pursuant to Rule 37.6, *amicus curiae* discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus curiae* make a monetary contribution to the preparation or submission of this brief. Letters from Petitioners and Respondent granting consent to the filing of this *amicus curiae* brief have been filed with this Court.

training the new EPA Director in the details of pesticide registration and regulation.

One of Harrison's more important duties while in the Insecticide and Rodenticide Branch was to create and edit the EPA instruction manual "General Information on Applying for Registration of Pesticides in the United States." That manual informed pesticide manufacturers and other prospective applicants how to fulfill the registration requirements of FIFRA and the Federal Food, Drug, and Cosmetic Act. That manual details the EPA pesticide registration process, regulations, and policies, and specifies the requirements for data compensation and labeling.

During his career, Harrison was awarded five EPA Bronze Medals for his work in pesticide regulation. He retired from government service in 1993, having spent the previous 27 years overseeing the registration of pesticides for the federal government. Upon his retirement and in recognition of his exceptional career service, he was awarded the EPA's Distinguished Career Gold Medal, the highest honor the Agency awards.

After retiring, Harrison began a pesticide consulting business to advise pesticide companies on the various aspects of pesticide regulation by the federal government. He has therefore kept abreast of pesticide registration developments. Due to his background and experience, he is intimately familiar with the EPA pesticide registration and label approval process, including the policy decisions involved with implementing virtually every nuance of the program. He submits this brief to demystify the pesticide registration process and to aid the Court in assessing the importance of how pesticides are registered.

SUMMARY OF THE ARGUMENT

The majority of courts to consider this issue have concluded that EPA waiver of regulation in the area of pesticide efficacy is "beside the point" and "irrelevant." By so superficially dismissing this crucial fact, those courts have exposed their fundamental lack of understanding of the EPA pesticide registration process. Analysis of the question before this Court should begin and end by recognizing the absence of EPA regulation of pesticide efficacy. Simply put, the EPA does not approve herbicide label claims regarding how well a product works. The EPA does not review whether the product actually injures the crops it was intended to assist. Without EPA review of pesticide efficacy or approval of its label-based efficacy claims, there simply is no federal regulation of pesticide efficacy. Without federal regulation, there can be no preemption.

ARGUMENT

I. Federal Pesticide Regulation Has Evolved Away From Evaluating Product Efficacy.

In its early years, pesticide regulation in this country was weak at best. Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 Yale J. on Reg. 369, 423 (1993). By the end of the 1960's, a House of Representatives subcommittee investigation concluded:

> Pesticide products had been approved for use without compliance with interdepartmental procedures for resolving safety questions; that they had been approved for uses practically certain to result in the illegal adulteration of food; that

> some labels approved for registration failed to inform users of possible hazards and provide accurate directions; that actions to cancel registered products were long delayed; that, despite completion of uncontested cancellation proceedings, hazardous products lingered in the marketing channels for years; and that conflicts of interest had clouded administrative decisions.

William H. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* 31 (1988) (citing H. R. REP. NO. 91-637, 91st Cong., 1st Sess. (1969)). These disclosures contributed in no small way to a 1970 government reorganization plan that stripped the United States Department of Agriculture of its authority to regulate chemical pesticides and transferred that power to the newly-established Environmental Protection Agency ("EPA"). *Id.*

Federal regulation of pesticides has grown more stringent on the EPA's watch. In 1972, Congress responded to "growing environmental and safety concerns" by "significantly strengthen[ing] FIFRA's registration and labeling standards." *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). These amendments "transformed FIFRA from a labeling law into a comprehensive regulatory statute." *Id.* (quoting *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991 (1984)). Under the 1972 amendments, Congress instructed the EPA to register a pesticide after evaluating its proposed label and determining that its "composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5)(A). Pesticide manufacturers were therefore required to submit massive quantities of documents so the EPA could substantiate the claims made on a proposed label. By 1977, the requirement that the EPA evaluate and

approve pesticide efficacy[2] claims had so thoroughly overburdened the Agency that Administrator Douglas M. Costle requested that Congress eliminate the requirement that the Agency review pesticide efficacy during the registration process. H. R. REP. NO. 95-343 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1974. On behalf of the EPA, Costle complained that "[t]he registration and reregistration process, which is the foundation of the program, has come to a virtual halt." H. R. REP. NO. 95-663 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1991.

In 1978, Congress reacted to the EPA's predicament by amending FIFRA and permitting the EPA to forego the time-consuming and resource-intensive evaluation of product efficacy. *See* 7 U.S.C. § 136a(c)(5) ("[i]n considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy"). Congress expected this efficacy waiver authority "to be used, in particular with respect to agricultural chemicals." H. R. REP. NO. 95-663, 95th Cong., 1st Sess. 19 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1992. For the past 26 years, the EPA "has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot be readily observed by the user. . . ." 40 C.F.R. §§ 158.640(b)(1); 158.540. Therefore,

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[2] As defined by the EPA, "efficacy" has two discrete components: product performance (whether the product controls the target pest) and target area phytotoxicity (whether the product harms the target crop). U.S. Inv. Br. 4, 13 (citing 40 C.F.R. §§158.540, 158.640).

although FIFRA still requires the EPA to register a pesticide after determining that "its composition is such as to warrant the proposed claims for it," the EPA no longer evaluates the efficacy of agricultural pesticides.

II. Under FIFRA, The EPA Does Not Evaluate Efficacy Of Agricultural Pesticides.

FIFRA charges the EPA with conducting four distinct registration reviews: initial registration; reregistration; experimental use permits; and special review. Fred Whitford, et al., *Pesticides and Ecological Risk Assessment* 11 (2003).[3] Initial registration of a pesticide is a two-step process and the same process applies to all applicants. *See* 7 U.S.C. § 136a(c). In the first step, the EPA decides whether a product meets the criteria for expedited review. If the product qualifies for expedited review, it reaches the second level of EPA analysis – the actual registration review – more quickly. If the product does not qualify, the manufacturer simply submits the product for conventional registration. Regardless of whether a product has qualified for expedited review, the second level of EPA review is the exact same for all products; the only difference is that products that do not qualify for expedited review have to wait longer in line.

The EPA publishes scientific testing regulations to ensure that when a product reaches the front of the line and its registration is decided by the EPA, the studies supporting its registration are complete and employ

[3] Because the pesticide at issue faced EPA scrutiny during the initial registration review process, this brief will address the EPA's waiver of efficacy data specific to that process.

premier scientific tests and methods. *See, e.g.*, 40 C.F.R. Part 160. Those regulations detail the testing required and how the studies are to be performed. *See id*. Advances in science and new experimental tools have yielded more complex and voluminous data for review, and the data commonly submitted for an initial pesticide registration frequently exceeds 10,000 pages. Whitford at 8. Those increased review responsibilities have understandably delayed the registration process and created a paradox under which the EPA is expected to conduct more intensive reviews and more quickly respond to an increased number of applications. *See id*. The EPA has attempted to alleviate the bottleneck of initial registration applications by developing several expedited review programs under which select products advance more quickly to the front of the line.

A. EPA Does Not Evaluate Efficacy When Granting Emergency Exemptions.

In emergency situations, the EPA may authorize the use of a previously unregistered pesticide. *See* 7 U.S.C. § 136p. This exemption, however, is limited in several ways. First, a federal or state agency must request the exemption. *See* 40 C.F.R. § 166.20(a). Second, the EPA must determine that emergency pest conditions exist, that is, a threat of significant economic loss, significant risk to the environment or a significant risk to endangered or threatened species or beneficial organisms. *See* 40 C.F.R. § 166.2. Third, the EPA must be able to establish a formal tolerance or limit on the amount of pesticide residues left on the treated area, especially if the pesticide residue could affect the food supply. *See* 40 C.F.R. § 166.25(a)(2). Fourth, the emergency exemption may be authorized for

"only as long as is necessary to control the pest or conditions causing the emergency." 40 C.F.R. § 166.45.

On February 24, 1999, the Texas Department of Agriculture submitted an application for an emergency exemption to permit Strongarm "to treat up to 184,000 acres of peanuts, to control broadleaf weeds" in Texas. 64 Fed. Reg. 9152 (Feb. 24, 1999). This application proposed the use of diclosulam, the active ingredient in Strongarm, a chemical that had not been previously registered by the EPA. *Id.* The EPA denied that emergency application on March 9, 1999, and Dow was forced to pursue an alternate method of expedited registration review. *See* 65 Fed. Reg. 3691, 3707 (2000) ("[t]his request was denied because adequate alternatives are available to control the weeds specified in this request.")

B. EPA Considers Product Efficacy In A Limited Manner Under The Reduced-Risk Initiative, But Not In Registering The Pesticide.

The EPA's most notable expedited review program, the "Reduced-Risk Initiative," went into effect on an interim basis in July 1993 and was finalized in September 1997. OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 97-3 § 4 (Sept. 4, 1997), available at http://www.epa.gov/oppmsd1/PR_Notices/pr97-3.html. Under this program, "lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives" are guided through the backlog of registration applications and receive expedited review. *Id.* at § 1. Products that meet the reduced-risk criteria receive a registration decision from the EPA in an average of 14 months, compared to

38 months for conventional pesticides that do not qualify. *Id.* at § 4. During the 50 months the EPA applied the interim reduced-risk criteria, applicants sent 39 submissions to the EPA for consideration as reduced-risk pesticides. *Id.* Of that number, 22 were accepted as reduced-risk candidates[4] and 16

[4] In descending order, the factors that contributed most significantly to the EPA's decision to grant an application reduced-risk status during that 50-month period were:

- Human Health Effects
  - very low mammalian toxicity
  - toxicity generally lower than alternatives
  - displaces chemicals that pose potential human health concerns
  - reduces exposure to mixers, loaders, applicators, and reentry workers
- Non-Target Organism Effects (Birds)
  - very low toxicity to birds
  - very low toxicity to honeybees
  - significantly less toxicity/risk to birds than alternatives
  - not harmful to beneficial insects, highly selective pest impacts
- Non-Target Organism Effects (Fish)
  - very low toxicity to fish
  - less toxicity/risk to fish than alternatives
  - potential toxicity/risk to fish mitigatable
  - similar toxicity to fish as alternatives but significantly less exposure
- Groundwater
  - low potential for groundwater contamination
  - low drift, runoff potential
  - runoff mitigatable
- Lower Use Rates Than Alternatives, Fewer Applications
- Low Pest Resistance Potential
- Highly Compatible With IPM (Integrated Pest Management)
- Efficacy

Id. at § 5.

were rejected.[5] *Id.* Out of the 22 accepted reduced-risk submissions, 14 were eventually registered. *Id.*

Strongarm was not approved for expedited review under the Reduced-Risk Initiative. Stephen Schaible, the conventional reduced-risk pesticide program coordinator, advised *amicus curiae* that Strongarm was originally submitted under the Reduced-Risk Initiative, but its application was denied because it did not meet the reduced-risk criteria. The requirements of submitting efficacy information under the Reduced-Risk Initiative may be misleading, and understanding exactly what is reviewed under the Reduced-Risk Initiative and why is complicated. *Amicus curiae* was one of the initial proponents of the reduced-risk criteria and has personal experience with its practical applications. To avoid potential confusion, this brief will attempt to explain the Reduced-Risk Initiative

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[5] Also in descending order, the factors that contributed most significantly to the EPA's decision to deny an application reduced-risk status during that time were:

° Human Health Effects
- inadequate/inappropriate comparisons with alternatives
- inadequate documentation of effects
- human health risk reduction case weak

° Non-Target Organism Effects (Birds and Fish)
- toxic to birds
- toxic to fish
- risk reduction case inadequate when compared to alternatives

° Potential Groundwater Problems

° Unlikely To Displace Higher Risk Alternatives

° Lack Of Efficacy Data

° Phytotoxicity

Id. at § 5.

even though Strongarm was not approved under that process.

1. Pesticides Are Not Registered Under The Reduced-Risk Initiative.

All chemical pesticide applications ultimately face the same registration review regardless of whether they are submitted under the Reduced-Risk Initiative, a different "fast track" program in effect for registration of conventional pesticides, or the conventional registration program. 7 U.S.C. § 136a(c)(2)(A). The only benefit of the Reduced-Risk Initiative is expedited review and the possibility of accelerated registration. P.R. Notice 97-3 § 6 (noting that if the EPA "decides that a pesticide qualifies for reduced-risk status, then it will further expedite review of the remainder of the application for registration"). Regardless of the process by which an application reaches the front of the line, all applications are treated the same in the second step of EPA review – the registration process.

2. EPA Waives Efficacy Review In Registering Agricultural Pesticides.

One of the objectives of the Reduced-Risk Initiative is to displace more harmful pesticides. *See id.* at § 1. To evaluate whether consumers will purchase a new, safer product and thereby displace a more harmful one, the EPA is required to perform some review of whether the product will in fact work. *See* 57 Fed. Reg. 32140 (July 20, 1992) (stating that the "specific goal of such [reduced-risk] policies would be to encourage the registration of lower risk substitutes for existing high-risk pesticides"). In order

to decide whether an applicant qualifies for the benefits of the Reduced-Risk Initiative, the EPA requires the applicant to submit a summary of comparative performance or efficacy data – but not the supporting data itself.[6] P.R. Notice 97-3 § 7(G). The results of an applicant's efficacy studies, as represented by the summary of comparative performance data, affect whether that applicant qualifies for the benefit of expedited review under the Reduced-Risk Initiative. *See id.* at § 5. However, once the applicant passes the first step of qualifying for the Reduced-Risk Initiative, the EPA has no further use for the efficacy summaries and does not use that information in the registration process. *See id.*

As with any scientific data, much of the data that is required to be submitted for registration may be read in more than one way. The EPA requires applicants to submit data generated by standard testing against a collection of generic plants and plant families intended to generally represent plants found in the environment. *See, e.g., id.* at § 7(G). This data may, in some instances, be read to express an applicant's findings on product efficacy. *See id.* However, the EPA uses these generic tests now, as in the past, only to assess whether a new pesticide will pose an unreasonable risk to humans, non-target plants and organisms, or the environment in general. *Id.* at § 1. Although the data compiled in some of these studies may also be read to express findings as to product performance or target area phytotoxicity, the EPA does not, and due to

[6] For several years, if an applicant submitted the data supporting its summary in addition to the summary itself, the EPA's practice was to send that material back to the applicant.

insufficient funding, cannot examine those studies for that result during the registration review process.

Importantly, the EPA provides a great deal of "flexibility in requiring (or not requiring) data" and expressly offers to "waive data requirements on a case-by-case basis in response to specific written requests by applicants." 40 C.F.R. §§ 158.35, 158.45. Under the Reduced-Risk Initiative, the EPA specifically permits an applicant to substitute "reasoning as to why [required data] should not be considered in the Agency's decision" for the data itself. P.R. Notice 97-3 § 7. An applicant may, therefore, "provide a short rationale describing" the reasons it should not have to provide information required by the Reduced-Risk Initiative, including, presumably, the summary of comparative performance or efficacy data. *See id.* These provisions illustrate that the absence of information required by the Reduced-Risk Initiative may not serve as a bar to registration and even without all the required information, an applicant may still be considered for expedited review. *See id.* For that reason, applying for expedited review under the Reduced-Risk Initiative does not constitute a regulation of efficacy.

The benefits of expedited review under the Reduced-Risk Initiative are available only for those products that demonstrate a reduced risk to human health and the environment than existing alternatives. *See id.* at § 1. Requiring applicants under the Reduced-Risk Initiative to submit a summary of efficacy data but not the data themselves is the only way the resource-limited EPA can ensure that applicants can substantiate their claim to have produced a safer pesticide and their entitlement to expedited review. If the EPA did not require applicants to produce a summary of this data, then it would have no

way of knowing whether the applicant had even tested the product and would lack the ability to gauge the applicant's entitlement to the benefits of the Reduced-Risk Initiative. An applicant who claims that applying for the purely voluntary Reduced-Risk Initiative constitutes some EPA regulation of product efficacy demonstrates a lack of understanding of the Reduced-Risk Initiative and its process.

C. Efficacy Is Irrelevant In Granting "Me Too" Registrations.

Under FIFRA, the EPA may conditionally register a pesticide if it determines that "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof or differ only in ways that would not significantly increase the risk of unreasonable adverse effects of the environment." 7 U.S.C. § 136a(c)(7)(A). This conditional registration, also called "me too" registration, is designed for products that are identical to a product previously registered by the EPA. *See* 40 C.F.R. § 152.113(b). To qualify for "me too" registration, an applicant "shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5)." *Id*. Paragraph 5 waives the requirement of submitting efficacy data. *See* 7 U.S.C. § 136a(c)(5).

When the EPA issued its March 8, 2000 registration of Strongarm, it stated that Strongarm was conditionally registered under the "me too" program. However, Strongarm's active ingredient, diclosulam, was neither identical to any currently registered pesticide, nor was it different from a currently registered pesticide only in ways that would not significantly increase the risk of unreasonable

adverse effects on the environment. That confusion prompted *amicus curiae* to contact Jim Tompkins, a Product Manager in the Herbicide Branch of the EPA's Registration Division and the signatory of Strongarm's notice of pesticide registration. Tompkins explained that Strongarm was actually registered under the "fast track" conditional registration provisions of 7 U.S.C. § 136a(c)(7)(C) and not the "me too" provisions of 7 U.S.C. § 136a(c)(7)(A). Even if Strongarm had been registered under the "me too" program, however, the EPA would not have reviewed any efficacy data Dow submitted. *See* 7 U.S.C. § 136a(c)(5).

D. EPA Waives Efficacy Review For "Fast Track" Conditional Registrations.

On March 8, 2000, Strongarm was registered under the conditional registration provisions of 7 U.S.C. § 136a(c)(7)(C). Under that statute, the EPA:

> may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on other such conditions as the Administrator may prescribe.

7 U.S.C. § 136a(c)(7)(C). This "fast track" program for registering conventional pesticides is premised upon a

determination "that use of the pesticide during such period will not cause any unreasonable effects on the environment, and that use of the pesticide is in the public interest." *Id*. The conditions of Dow's registration of Strongarm required Dow to "submit and/or cite all data required for registration reregistration of your product under FIFRA sec. 3(c)(5)." Section 3(c)(5) specifically provides:

> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

7 U.S.C. § 136a(c)(5). Under this "fast track" program for registering conventional pesticides, as for all registration of chemical pesticides, the EPA has waived the evaluation of product performance and target area phytotoxicity.

E. The EPA Evaluates Efficacy In Only Two Situations, Neither Of Which Are Presented In This Case.

The EPA continues to evaluate efficacy data in two limited areas, neither of which are presented in this case. First, if the EPA considers canceling, denying, or reclassifying "registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment," then it will initiate special review

procedures under 40 C.F.R. Part 154. 40 C.F.R. § 154.1. Because the EPA did not initiate special review proceedings against Strongarm, it did not evaluate the product's efficacy claims. Second, the EPA evaluates efficacy data in certain public health situations if it is reported that the pesticide poses some unusual risk of harm to human health or the environment. 40 C.F.R. § 158.640(b)(1). This exception applies to products such as hospital disinfectants, where a lack of efficacy might allow proliferation of microorganisms that affect public health. H. R. REP. NO. 95-663, 95th Cong., 1st Sess. 19 (1977), *reprinted in* 1978 U.S.C.C.A.N. 1992. Strongarm was not found to affect public health or pose an unusual risk of harm to human health or the environment, so the EPA was not obligated to, and in fact did not, evaluate its efficacy claims.

F. Post-Registration Reporting Of Ineffective Products Falls Short Of Efficacy Regulation.

In its invitation brief on petition for writ of certiorari, the United States argued that the EPA has not abandoned all regulation of product efficacy. Brief of Amicus Curiae the United States on Petition for a Writ of Certiorari, 13 n.2, *Bates v. Dow AgroSciences LLC*, 332 F.3d 323 (5th Cir. 2002), *cert. granted*, 124 S. Ct. 2903 (No. 03-388). The United States argued that the EPA regulates product efficacy because manufacturers must "report to EPA when they learn that their products have harmed non-target organisms such as crops or persons, if the label does not provide adequate notice of the risk of such harm." 40 C.F.R. 159.184(a)(1). Logically, however, post-registration and post-injury reporting of efficacy problems does not act as government approval of efficacy claims during the registration process. This regulation does not require the

EPA to evaluate product efficacy before the label is approved or the product is registered. For those reasons, the post-registration obligation to report efficacy complaints does not equate government evaluation of product efficacy.

III. Although Applicants May Submit It, The EPA Does Not Consider Efficacy Data In Registering Pesticides.

In 1996, the EPA explained its "procedures in approving pesticide labels relating to the efficacy of agricultural pesticides . . . to correct a misunderstanding regarding the FIFRA label approval process that is reflected in a series of court decisions concerning the preemptive effect of FIFRA." OFFICE OF PESTICIDE PROGRAMS, U.S. EVTL. PROT. AGENCY, PESTICIDE REGULATION NOTICE 96-4 § 1 (June 3, 1996), available at http://www.epa.gov/oppmsd1/PR_Notices/pr96-4.html. In that notice, the EPA's Office of Pesticide Programs stated "[b]ecause efficacy data is not reviewed as part of the registration of agricultural pesticides, it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide." *Id.* at 3. The EPA went a step further and clarified:

> [T]hese registration requirement should not be read as reintroducing efficacy concerns into the label approval process. *Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficiency issues would come in through the back door of the label approval process.* Under the statute and its regulations, EPA still must determine in registering a pesticide if the pesticide's label complies with FIFRA or is misbranded but, unless EPA reinstates the requirement to submit efficacy data (either generally or with regard to a particular pesticide), that compliance and misbranding inquiry will generally not extend to the evaluation of the efficacy of the pesticide.

PESTICIDE REGULATION 96-4 § 3 (emphasis added).

Under C.F.R. §§ 158.540 and 158.640(b)(1), the EPA requires all manufacturers to develop and maintain data supporting their efficacy claims. However, even the United States recognized that [g]enerally, EPA does not independently evaluate a registrant's product efficacy claims pertaining to agricultural pesticides." U.S. Inv. Br. 13 n.2. The only agricultural pesticides for which the EPA takes efficacy into account in the registration process are those that "claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user. . . ." 40 C.F.R. § 158.640(b)(1). These regulations require pesticide manufacturers to compile and maintain efficacy data, but they do not require the EPA to evaluate the efficacy data before registering the pesticide or approving the label.

Many manufacturers have argued that because they voluntarily submitted efficacy data to the EPA during the registration process, the EPA reviewed their claims of product efficacy. Plainly, that argument misses the point that the EPA is under no obligation to review these documents and lacks the resources to evaluate them. If such an argument were embraced by this Court, it would give applicants an incentive to automatically deluge the EPA with data it does not want, need, or have the ability to review. The EPA's term for such production of data, "malicious compliance," describes its view of applicants who flood it with data in an effort to gain an advantage in the registration process. Such a construction "would have the perverse effect of granting complete immunity . . . to an

industry that, in the judgment of Congress, needed more stringent regulation." *Medtronic, Inc. v. Lohr*, 513 U.S. 470, 486 (1996). Logically, therefore, it cannot be said that submission of efficacy data equates to EPA review and approval of a product's efficacy claims.

CONCLUSION

"EPA regulations define 'the domain expressly preempted.'" *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21, 24 (Tex. 2002) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992)). In 1978, Congress waived the requirement that the EPA determine pesticide efficacy before registering that pesticide. That waiver was specifically intended for agricultural pesticides because the EPA recognized that the registrant, the user, and the USDA which insures agricultural crops are in a superior position to judge product efficacy. For more than a quarter century, the federal government has not regulated pesticide efficacy – not by registering a product, not by approving a label, and certainly not by receiving post-registration complaints. No federal agency examines whether a pesticide will control a target pest without injuring the crop to which it is applied. For those reasons, there is no federal regulation of agricultural pesticide efficacy. There can be no requirement in addition to or different from the federal regulation if there is no federal regulation. Without federal regulation, there can be no preemption.

Amicus curiae therefore urges this Court to reverse the judgment of the United States Court of Appeals for the Fifth Circuit and hold that the state law crop injury claims

pursued in this case are not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act.

Respectfully submitted,

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